2014-1434

In the
United States Court of Appeals
for the Federal Circuit

DEY, L.P., NOW KNOWN AS MYLAN SPECIALTY, L.P.,
and DEY, INC.,

Plaintiffs-Appellees,

v.

TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
and TEVA PHARMACEUTICALS USA, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the Northern District of West Virginia in Case No. 09-CV-87, Judge Irene M. Keeley.

NON-CONFIDENTIAL REPLY BRIEF OF DEFENDANTS-APPELLANTS TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and TEVA PHARMACEUTICALS USA, INC.

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November 19, 2014

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CERTIFICATE OF INTEREST

Counsel for Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. certifies the following:

1. The full name of every party or *amicus* represented by me is:

Teva Parenteral Medicines, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Teva Parenteral Medicines, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

The parent corporation of Teva Parenteral Medicines, Inc. is Sicor Inc., which in turn is owned by Teva Pharmaceuticals USA, Inc. The direct and indirect parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK, Teva Pharmaceutical Holdings Coöperatieve U.A., IVAX LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Parenteral Medicines, Inc. or Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. has no parent, and no publicly traded company owns 10% or more of Teva Pharmaceutical Industries Ltd.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus* now represented by me in the trial court or agency or are expected to appear in this court are:

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CONFIDENTIAL MATERIAL OMITTED

Confidential business and formulation information of Defendant-Appellant Teva, Plaintiff-Appellee Dey, and third party Sepracor that is the subject of the District Court's Protective Order has been redacted from pages 4, 7-8, and 12-13.

TABLE OF AUTHORITIES

Cases

Statutes

TABLE OF ABBREVIATIONS

Teva	Teva Parenteral Medicines, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.
Dey	Dey, L.P., now known as Mylan Specialty, L.P., and Dey, Inc.
TBr	Teva's opening brief on appeal
DBr	Dey's brief on appeal
Sepracor	Sepracor, Inc. (became Sunovion)
ALP	Automated Liquid Packaging (became Catalent)
Patents-in-Suit	U.S. Patent Nos. 6,667,344; 6,814,953; 7,348,362; and 7,462,645
'344 patent	U.S. Patent No. 6,667,344
'953 patent	U.S. Patent No. 6,814,953
'362 patent	U.S. Patent No. 7,348,362
'645 patent	U.S. Patent No. 7,462,645
A[number]	Joint Appendix [page]
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
Asserted Claims	'344 patent claims 3, 34, 40, 65, 74, 104, 116; '953 patent claims 76, 106, 112, 136, 160, 163; '362 patent claims 1, 2, 3, 4, 6, 8, 9, 10, 12, 15; '645 patent claims 2, 3, 6, 8, 9
POSA	person of ordinary skill in the art
Sepracor Lots	Sepracor Lots 02797A, 01799B, and 03501A
First Lots	Sepracor Lots 02797A and 01799B
First Patent Family	'344 and '953 patents
Second Patent Family	'362 and '645 patents
First Patent Family Asserted Claims	'344 patent claims 3, 34, 40, 65, 74, 104, 116; '953 patent claims 76, 106, 112, 136, 160, 163
Second Patent Family Asserted Claims	'362 patent claims 1, 2, 3, 4, 6, 8, 9, 10, 12, 15; '645 patent claims 2, 3, 6, 8, 9
Arformoterol	An enantiomer of formoterol
COPD	chronic obstructive pulmonary disorder
MDI	metered dose inhaler

SUMMARY OF REPLY ARGUMENT

The District Court erred in three ways in construing the Asserted Claims. First, the District Court erred by considering "photostability" irrelevant to whether Teva's product infringes. As a result, the District Court erred in finding infringement. Second, at trial, the District Court adopted a new construction of "stable during long term storage" by interpreting the limitation as requiring an estimated shelf-life under consecutive storage and usage conditions. Third, the District Court erred by construing the claim term "pharmaceutical composition" as not requiring a "stable composition." The District Court compounded these errors by inconsistently applying its own constructions with respect to stability.

The District Court erred in concluding the Sepracor purchases were not sales under 35 U.S.C. §102(b). ALP sold Sepracor a finished packaged product, arformoterol inhalation solution. Whether Sepracor maintained ownership of the arformoterol powder used to formulate the solution is immaterial to the sale. Nor is secrecy an issue; Sepracor and ALP are unrelated third parties to Dey and thus constitute the public with respect to Dey. While Dey contests the sales, Dey concedes that such sales would render at least the Second Patent Family Asserted Claims invalid.

The prior art teaches all the elements of the Asserted Claims with or without these sales. A POSA would have been motivated to make an aqueous formoterol

inhalation solution and would have expected to achieve a stable solution, since the prior art compositions have the same ingredients as required by the Asserted Claims, and inherently they have the same stability.

REPLY ARGUMENT

I. The District Court Erred in Finding Infringement

A. "Aqueous Stability" is Inextricable from "Photostability"

The District Court erred in holding photostability irrelevant to the "long term stability" required by claims 1 and 65 of the '344 patent. (A152.) Dey's attempt to support the District Court by arguing that the Asserted Claims require only aqueous stability but not photostability is pure sophistry. (DBr 20-21.) Dey's semantics obscure the immutable chemical properties of aqueous formoterol solutions. When formoterol is dissolved in water the formoterol molecule chemically degrades upon exposure to visible light and/or UV radiation, just as it chemically degrades in response to higher temperatures. (A23282; A23508; A23588; A23626/191:4-9 (Laskar); A23312-A23322.) *Aqueous formoterol is unstable, in part because it is not photostable.*

This Court should construe "stability" to include photostability. Under this construction, Teva's product is not stable and does not infringe claims 1 and 65 of the '344 patent. (*See* A23634-40; A22105-06; TBr 19.)

B. Claims 1 and 65 Require a Composition Stable During Long Term Storage Independent of Packaging Material

Teva's product does not infringe claims 1 and 65 of the '344 patent because the solution is not stable independent of light protective packaging. A dependent claim that adds a limitation not present in the independent claim gives rise to a presumption that the limitation is not present in the independent claim. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005). Claim 1 defines a formoterol solution that is stable with no required protective packaging. Claim 65 adds a "packaging material" requirement, giving rise to the presumption that packaging material is not an element required by claim 1, and thus the solution in claim 1 must be stable without protective packaging. (TBr 27.)

Dey fails to offer palpable reasoning why the presumption should be ignored, providing only conclusory statements. (DBr 23-24.) However, Dey's own arguments about its alleged invention undermine these contentions. According to Dey's own construction, adopted by the Court, "pharmaceutical composition" refers to a "medicinal formulation containing an active drug and inert excipients" with no mention of packaging. (A103.) Dey discusses the development of its invention as optimizing excipient concentrations and pH with no discussion of protective packaging. (DBr 9-10.) Dey describes the resultant composition as satisfying the stability limitations of claims, again with no reference to packaging. (DBr 11.) Dey also unambiguously states: "it is the

inactive ingredients in Perforomist® – its buffer and tonicity adjusting agent at specific concentrations – that make aqueous formoterol stable." (DBr 58.) Dey's admissions demonstrate that the District Court erred in construing claims 1 and 65, and that decision must be reversed.

[redacted] Further, a POSA would not interpret "packaging material" as requiring an opaque material given the broad scope of packaging materials in the '344 patent specification, which includes bottles and tubes. (A181/16:53-61.) As Teva's product is not "stable during long term storage" independent of light-protective "packaging material," it cannot infringe claim 1 or claim 65 of the '344 patent.

II. The District Court Incorrectly Adopted Dey's New Construction of "Stable During Long Term Storage" When Deciding Invalidity

The District Court applied two different constructions of "stable during long term storage" – one in the infringement analysis and a second in the invalidity analysis. This fundamental error of claim construction compels the conclusion that the decisions on both invalidity and infringement must be reversed – "it is axiomatic that claims are construed the same way for both invalidity and

infringement." *Source Search Techs. LLC v. LendingTree, LLC*, 588 F.3d 1063, 1075 (Fed. Cir. 2009); *see also Ferring B.V. v. Watson Labs., Inc. – Fla.*, 764 F.3d 1401, 1411 (Fed. Cir. 2014) (reversible error where district court does not follow its own claim construction).

Early in the case, the Court adopted the parties' agreed-upon construction of "stable during long term storage" to mean: "the composition has an estimated shelf-life of greater than 1, 2, or 3 months usage time at 25°C and greater than or equal to 1, 2 or 3 years storage time at 5°C." (A118.) The parties used this very definition throughout expert discovery, and the parties and the Court used this definition for summary judgment. (A124.) Based on this construction, and the Court's summary judgment decision excluding photostability from the infringement analysis pertaining to claims 1 and 65 of the '344 patent, Teva stipulated to infringement of the remaining Asserted Claims. (A166-68.)

Dey, for the first time at trial, proffered a new interpretation of the limitation "stable during long term storage" by contending that the storage and usage conditions must be tested *consecutively* to satisfy the claims. (A25567-68/117:8-118:21; A25654-56/196:9-198:10 (Chaudry); A27049-50/1564:20-1565:14.) This new interpretation changed the meaning of the claims. The Court erroneously decided validity according to this new construction. (A16-17.)

If the District Court had not adopted Dey's new construction at trial, the Patents-in-Suit would likely have been found invalid. Dey echoes the District Court's findings by admitting Dey's testing of formoterol in pure water showed that after six months storage at 5°C, 91% of the initial formoterol remained and that after six months at room temperature, 80% of the initial formoterol remained. (DBr 10-11; *see* A16.) If the results at 5°C were extrapolated to 1 year, as both Dey and the District Court do, one would expect 18-20% degradation. (DBr 11; A16.) The specifications define the stability of a composition as the length of time at a given temperature that greater than 80% of the initial amount of formoterol remains. (A176/5:30-38; A261/5:37-45.) Accordingly, based on Dey's own testing, formoterol in water satisfies the limitation "stable during long term storage" if consecutive storage and usage conditions are not required. Dey and the District Court proceed to disregard the original construction and distinguish the stability of the claimed compositions from "formoterol in pure water" based on alleged stability under *consecutive* storage and usage conditions. (DBr 10-11; A16.)

Dey seeks to support the District Court by rewriting history. Dey asserts that consecutive testing of storage and usage conditions was the construction adopted by the District Court and agreed upon by the parties all along. Dey is wrong. Neither party interpreted the "and" in the storage and usage conditions to

indicate consecutive testing as Dey now argues. Both parties and the Court understood the claims to mean that the pharmaceutical composition must be capable of independently satisfying both separate stability requirements, not that the stability conditions are consecutive. At trial, *Dey's* expert Dr. Barnes testified that he understood the storage and usage conditions as not consecutive. (A25835/337:7-20.) Replacing "and" with "or" as Dey suggests (DBr 26), would have made the two conditions alternatives – an incorrect construction that Teva has never asserted.

Dey also contends Teva could have argued against the new construction at summary judgment. (DBr 26.) Again, Dey is wrong since that construction never arose until trial.[1] Nothing in the summary judgment record suggests that the parties or the Court had any contemporaneous understanding that the claims required the storage and usage conditions to be tested consecutively. Importantly, neither Teva, Dey, nor the Court ever mentioned consecutive testing when discussing the claim term "stable during long term storage." (A138-139; A21067; A21742-50; A24113-A24115.)

If Dey's new construction had been before the parties and the Court, consecutive testing would have been a central issue to infringement. [redacted]

[redacted]

[1] Dey engaged new counsel on April 30, 2014, shortly before trial.

[redacted]

Dey now contends that the District Court's ruling should stand because of newly presented consecutive testing data for Perforomist®. (DBr 28-29.) That Dey did not present this data at summary judgment underscores that even Dey did not read the claims as requiring consecutive storage and usage conditions. Additionally, Dey cannot, on appeal, rely on evidence that was not before the District Court at summary judgment. *See Meyer Intellectual Prop. Ltd. v. Bodum, Inc*., 690 F.3d 1354, 1371 (Fed. Cir. 2012). Even had Dey presented this argument, it would have been incorrect for the District Court to have drawn a factual inference *against* Teva, the nonmoving party, that its ANDA product infringes based on data for another product. *Id*. at 1370. Dey must prove that *Teva's* product infringes. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570 (Fed. Cir. 1997).

III. The "Pharmaceutical Composition" Must Be Stable

Both Dey and the District Court changed positions regarding the stability of the claimed "pharmaceutical compositions" to suit the situation. When deciding

infringement, the District Court construed "pharmaceutical composition" to not require stability. When deciding invalidity, the District Court changed course and treated *all* claims as requiring stable compositions. This is reversible error. *Source Search*, 588 F.3d at 1075; *see also Ferring*, 764 F.3d at 1411.

Dey emphasizes what it calls the ordinary meaning of the asserted claim term "pharmaceutical composition." (DBr 17.) However, a more particular meaning should be adopted when the inventor has disavowed claim scope by "distinguish[ing] that term from prior art on the basis of a particular embodiment, expressly disclaim[ing] subject matter, or describ[ing] a particular embodiment as important to the invention." *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009).

Here, Dey disavowed pharmaceutical compositions that are not "stable." The law is clear: "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). The only compositions described in the Patents-in-Suit are stable compositions. (A174/2:17-18, 24-27, 42-47; A259/2:23-26, 41-42.) The compositions in the Patents-in-Suit are distinguished from prior

art based on stability. (A174/2:9-15; A177/7:44-46, 7:65-8:8; A259/2:12-17; A262/7:55-57, 8:25-37.) The patentees undoubtedly intended to exclude unstable compositions. *See Edwards Lifesciences*, 582 F.3d at 1329; *see also AstraZeneca AB v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004).

Further, Dey disavowed unstable compositions during prosecution. Dey characterized its compositions as stable and distinguished them from prior art on that basis. *See Ormco Corp. v. Align Tech. Inc.*, 498 F.3d 1307, 1316 (Fed. Cir. 2007). Dey consistently cited stability as a feature distinguishing *all* its claimed compositions from the prior art both during prosecution and throughout this litigation, most recently in its answering brief. (A2507; A2512; A2516; A7539; A12150-51; A12151 n.1; A12153; A14095/12:5-17; A14171/88:1-4; A14174/91:17-19; DBr 14, 30, 32, 52, 58.) For instance, Dey unambiguously states "[t]he patents-in-suit claim 'pharmaceutical compositions' that address the problem that had plagued previous attempts to develop ready-to-use inhalation formulations of formoterol: formoterol degrades in water, making it impossible to store it in a solution that a patient can use in a nebulizer to form a mist." (DBr 14.)

Attempting to unduly broaden the scope of "pharmaceutical composition," which occurs in all Asserted Claims, Dey argues "the claims contain no limitation relating to stability other than that requiring compositions that are 'stable during long term storage'." (DBr 18.) The District Court echoed this sentiment at claim

construction and in finding infringement. (A103, A153.) However, critically, *not all the asserted claims contain the limitation "stable during long term storage," and some contain no stated stability limitation*.[2] Despite the absence of stated stability limitations in some claims, Dey repeatedly distinguished *all* asserted claims from the prior art based on stability and the District Court followed along. (A54-55; DBr 14, 30, 32, 52, 58.) Neither the District Court nor Dey treat claims with the limitation "stable during long term storage" as distinct from claims without the limitation when discussing invalidity. The inescapable conclusion is that notwithstanding the claim construction, Dey and the District Court now read each of the claimed "pharmaceutical compositions" to be a stable composition – just as Teva has argued all along.

This Court should overrule the District Court's claim construction and hold that *all* of the "pharmaceutical compositions" recited in the Asserted Claims must be stable.

IV. The Claimed Invention Was On Sale

Dey argues the alleged invention was not "on sale" because Sepracor owned the arformoterol used to make the Sepracor Lots. (DBr 66-70.) Dey also contends

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[2] Claim 116 of the '344 patent and all Second Patent Family Asserted Claims do not contain the term "stable during long term storage." Claims 4, 8, 12 (when depending from 8) and 15 (when depending from 8) of the '362 patent and claims 6, 8 and 9 (when depending from claim 1) of the '645 patent do not contain a specific stability limitation.

the Sepracor transactions are irrelevant because they were not public.[3] (DBr 70-72.) Dey is wrong on both counts.

A. Sepracor Purchased Inhalation Solution from ALP in a Commercial Sale

Ownership of the bulk arformoterol used in the inhalation solution is irrelevant to "on sale." Even if the buyer has ownership rights in the product, a transaction passing rights of property for consideration is still a sale. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890-91 (Fed. Cir. 1999), where the buyer (Brasseler) jointly developed surgical saw blades with a manufacturer, who then manufactured the blades and sold them to Brasseler. *Id.* at 889. In holding the blades to be "on sale," the Court rejected Brasseler's argument that the transaction was not a sale because Brasseler was the "equitable owner" of the invention at the time of the sale. *Id.* at 891. Here, Sepracor's ownership of the bulk arformoterol powder that ALP formulated into an inhalation solution, packaged, and sold to Sepracor (A7821/35:14-23; A26840-41/1360:15-1361:24; A26842-43/1362:4-1363:8; A26847-49/1367:18-1369:25 (Wald)) does not change the fact of the sale of the inhalation solution by ALP to Sepracor. Like in *Brasseler*, "[t]he transaction was invoiced as a sale of product [redacted]

[3] Dey does not dispute Teva's contention that the District Court erred in concluding that the Sepracor transactions were not commercial offers for sale based on experimental use. (DBr 65 n.14; TBr 35.)

[redacted], and the parties understood the transaction to be such." *Brasseler*, 182 F.3d at 891.

Dey's reliance on *Trading Technologies International, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010) is misplaced. Unlike *eSpeed*, Sepracor did not contract with a developer to provide hourly services. 595 F.3d at 1361. Sepracor purchased an inhalation solution – a product – according to its agreement with ALP. (A470; A473-75; A896; A676-78; A1481-85; A7821/35:14-23; A26840-41/1360:15-1361:24; A26842-43/1362:4-1363:8; A26847-49/1367:18-1369:25 (Wald).)

Dey's wedding dress analogy is inapt. (DBr 67-68.) Unlike the wedding dress in Dey's story, which is returned to the owner in the same form it was dropped off, *i.e.*, still a dress, but clean and packaged, Sepracor's bulk arformoterol powder was converted into something entirely new – arformoterol inhalation solution. The inhalation solution did not exist before ALP formulated arformoterol with excipients to form the solution, which it then packaged and sold to Sepracor. (A7821/35:14-23; A26840-41/1360:5-1361:24; A26853-54/1373:23-1374:5 (Wald).) Arformoterol powder alone could not be administered to patients and was essentially useless until ALP made it into the inhalation solution product sold to Sepracor, a product suitable for administration to patients to treat COPD. (A7825-26/142:20-145:15; A7829/187:24-188:4 (Wald).)

Dey attempts to create sympathy for small pharmaceutical companies, which would, as Dey put it, be disadvantaged by Teva's interpretation of the Sepracor transactions. (DBr 69-70.) Dey's tale of woe misses the mark. Even small pharmaceutical companies seeking to outsource manufacturing or packaging can readily protect themselves from the "on sale" bar by timely filing their patent applications.

B. The Sale Need Not Be Public

Dey also confuses "public use" and "on sale," and the cases on which Dey relies are not on point. (DBr 70-72.) *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1371 (Fed. Cir. 1998) is about whether a *use* was public; it is not about a sale. (DBr 70.) And, as explained in *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1582 (Fed. Cir. 1986), *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) "does not support the broad proposition that the 'secret' commercialization of an invention by a third party creates no bar." Rather, "the question is not whether the sale, even a third party sale, 'discloses' the invention at the time of the sale, but whether the sale relates to a device that *embodies* the invention." *Id.* at 1583 (emphasis in original) (citations omitted). (TBr 36.)

Ignoring the holding in *J.A. LaPorte*, Dey attempts to distinguish the present case, apparently arguing that the sale could invalidate the claims only because the

inventor knew of it. (DBr 71.) However, the inventor's knowledge of the sale was not critical to the Court's finding that a sale took place. *J.A. LaPorte*, 787 F.2d at 1583. Dey also asserts that the present situation differs from *J.A. LaPorte* because its alleged invention was not discoverable from the product sold. (DBr 71-72.) Dey's argument is inconsequential. That the product ALP sold to Sepracor *embodied* an aqueous arformoterol inhalation solution and was to be used for the treatment of COPD is sufficient. *See J.A. LaPorte*, 787 F.2d at 1583. (A26149-52/683:8-686:3 (Myrdal); A26239-40/773:10-774:18; A26391-93/918:24-920:15 (Hendeles).)

In addition, regarding Dey, both ALP and Sepracor were the public, so an aqueous arformoterol inhalation solution, embodied in the Sepracor Lots, was in the public's hands. This is analogous to *J.A. LaPorte*, where the Court noted that the third-party buyer of the claimed invention "was a member of the relevant public," providing further support for its finding that the third-party sale invalidated the claims. 787 F.2d at 1583. Once the public has possession of the invention, as ALP and Sepracor did, Dey should not be able to remove that invention from the public with its patents.

V. Teva Has Shown that the Asserted Claims Are Anticipated and/or Obvious

All the elements of the Asserted Claims were present in, or were merely obvious variations of, the Sepracor Lots that are prior art to the Patents-in-Suit by

virtue of their sale by ALP to Sepracor (*see supra* Section IV). The Sepracor Lots are also evidence of the simultaneous "invention" by Dey and Sepracor of an aqueous formoterol inhalation solution, and provide evidence that the Asserted Claims are obvious. Additionally, prior art, including Foradil® inhalation powder, teaches or suggests all the elements of the Asserted Claims. A POSA would have been motivated to make a formoterol inhalation solution and would have reasonably expected to succeed in doing so. Considered separately or in combination, these sources anticipate and/or render obvious all the Asserted Claims.

A. Sepracor Lots Render the Asserted Claims Invalid

Because the Sepracor transactions were sales of the claimed invention, all the Asserted Claims are invalid as anticipated and/or obvious over the sales of the Sepracor Lots. Dey admits that Lot 3501A "would anticipate the Asserted Claims of the Second [Patent] Family." (DBr 72.) Dey also does not contest that the First Patent Family Asserted Claims are obvious over the First Lots, contending only that the First Lots do not anticipate the Asserted Claims. (DBr 72-77.)

The "differences" Dey asserts between the First Lots and the First Patent Family Asserted Claims do not render the claims patentable. Dey's "differences" relate to six elements: concentration, volume and unit dose packaging, mixtures of enantiomers and stereoisomers, buffer concentration, suitability for administration

without dilution, and stability. (DBr 72-77.) The last two are not differences at all. The evidence of record shows each of these elements was known in the art, and a POSA would have been motivated to combine the elements to arrive at the claimed invention with a reasonable expectation of success in doing so. (A26149-50/683:8-684:8 (Myrdal); A26262-65/796:15-799:15; A26281-83/815:17-817:22; A26291/825:4-16; A26293-95/827:21-828:14, 829:7-22; A26298-99/832:13-833:4; A26302-04/836:14-838:11; A26323-24/857:11-858:14; A26374-77/901:18-904:22; A26390-403/917:4-930:5; A26406-08/933:1-935:17 (Hendeles).)

Concentration

Dey argues that the First Lots do not anticipate the Asserted Claims that specify a concentration range of formoterol free base. (DBr 73.) Dey thus concedes that the First Lots, at 100 and 96 μg/ml formoterol, anticipate the formoterol concentrations in claims 3, 34, 65, and 74 of the ’344 patent, and 76, 106, and 136 of the ’953 patent, which contain no express concentration range.

For claims 40, 104, and 116 of the ’344 patent, and 112, 160, and 163 of the ’953 patent, which specify formoterol concentration, Teva’s unrebutted evidence shows that the claimed concentration was obtained by routine optimization determined during clinical trials. (TBr 12; DBr 41-43, 73.) Dey’s contention that the claimed narrower concentrations were chosen during reexamination of the First Patent Family (DBr 42-43) epitomizes routine optimization. The claims narrowing

the concentration ranges were not presented until after the reexaminations commenced in 2009 (A189; A231), about six years after the FDA suggested that concentrations similar to those in Foradil® should be used, and only after Dey subsequently tested lower formoterol concentrations based on suggestions by the FDA. (A25846-54/388:5-396:19 (Barnes); A32466-74; A35730-32.)

Volume and Unit Dose Packaging

Only claims 65, 104, and 116 of the '344 patent and claims 160 and 163 of the '953 patent require a unit dose and/or specify a volume for the unit dose. (DBr 74 n.18.) Nothing about the unit dose or volume makes the claims patentable. Packaging inhalation solutions for unit dose administration in volumes of about 2-3 ml was well known in the art. (TBr 17, 54-55.) Dey presented no evidence that the volume and unit dose packaging produced any unexpected results. (DBr 73-74; TBr 17.) In addition, the volumes of the First Lots anticipate the remaining First Patent Family Asserted Claims, which do not specify unit dose or volume. (TBr 10; DBr 74 n.18.)

Mixtures of Enantiomers and Stereoisomers

Claim 104 of the '344 patent and claim 160 of the '953 patent are the only First Patent Family Asserted Claims that require formoterol to be present as a mixture of enantiomers or stereoisomers. (DBr 74 n.19.) The specifications of the First Patent Family define formoterol broadly to include the racemic mixture,

stereoisomers, and single enantiomers, such as arformoterol. (A175/4:48-55.) And, formoterol as an enantiomeric mixture was commercialized in Foradil®. (TBr 53-54.) Dey presented no evidence that the mixture of enantiomers provides any unexpected advantages over prior art. (DBr 74.) Moreover, the First Lots contain arformoterol, which is within all the other First Patent Family Asserted Claims. (TBr 8-10; DBr 74 n.19.)

Claim 116 of the '344 patent requires formoterol fumarate dihydrate. (A211.) Dey presented no evidence that formoterol fumarate dihydrate provides any unexpected advantages over other salts of formoterol.

Buffer Concentration

All the First Patent Family Asserted Claims except claim 74 of the '344 patent and claim 136 of the '953 patent cover any buffer concentration. (DBr 74 n.20.) The 5-mM citrate buffer concentration of the First Lots anticipates the buffer concentration in all but those two First Patent Family Asserted Claims. (A26149-50/683:8-684:8 (Myrdal).) Regarding claims 74 and 136, even Dey admits that the buffer concentration does not affect stability in formoterol solutions having a pH from 4.6-5.6 (DBr 9), which encompasses the First Lots' pH 5. (A26149-50/683:8-684:8 (Myrdal).) Once the pH is set at the level that provides the greatest stability for the formoterol solution, a pH known from the prior art

(A1079/20:1-3; A304/38:1-9), optimizing buffer concentration is routine for a POSA. (TBr 52-53.)

Suitable for Administration Without Dilution

Although the First Lots were diluted before administration during clinical trials, they were *suitable* for administration without dilution as the claims require, and could have been administered without dilution. (A7825-26/142:16-144:24 (Wald); A26282-83/816:21-817:22; (Hendeles); *see also* A177/8:46-67; A13895-96/85:3-90:13 (Chaudry).) As the District Court noted during claim construction, "it is irrelevant … whether an end user mixes or dilutes them further because it is at the time of manufacture that they must be 'ready to administer, without mixing or diluting,'" (A93-94), as the First Lots were.

Dey's expert's testimony that doses of 139 μg/ml were too high for *long-term* treatment of COPD is immaterial. (A34; TBr 56.) There was no testimony that concentrations of 96 and 100 μg/ml in the First Lots were not "suitable for administration without dilution." Indeed, the formoterol concentration in the First Lots is lower than the 122 μg/ml Dey used in clinical studies. (A26260-62/794:2-796:14; A32379-80.)

Stability

Dey contends that the First Lots did not meet the stability requirements of the First Patent Family Asserted Claims (DBr 76-77), based on the District Court's

opinion that Dr. Myrdal's stability projections based on Sepracor data concerning the shelf life of the Sepracor Lots "fail to establish whether the Lots exhibit long-term stability." (A47). The District Court's finding was clearly erroneous, and Dey's contention is without foundation as it was premised on the new claim construction, requiring consecutive storage and usage testing. (*See supra* Section II.)

The District Court's opinion (A47) refers to Dr. Myrdal's testimony on cross-examination, at 704:1-706:21 (A26170-72), where Dr. Myrdal admits he did not calculate the amount of formoterol remaining after one year at 5°C and one month at 25°C, *consecutively*. That Dr. Myrdal did not make such a calculation is not surprising, since the District Court first interpreted long-term stability to require *consecutive* measurement of storage and usage conditions after trial. (*See supra* Section II.) Under the construction used for infringement, Dr. Myrdal testified that the Sepracor Lots meet the stability requirements of the claims. (TBr 11.)

B. Asserted Claims Are Also Obvious in View of Other Prior Art

Dey concedes that the prior art contained all the compositional elements of its claimed invention, but maintains that because the same art said formoterol was unstable in water, those disclosures would not lead a POSA to the invention. (DBr 40-41.) The prior art teaches that formoterol is unstable in water – *at room*

temperature. (A11-12; A1079/20:3-6; A25778-79/320:6-321:6 (Barnes).) Although the prior art did not measure the stability of its aqueous formoterol formulations under refrigerated conditions, the prior art recognized that refrigeration increases the stability of compounds subject to hydrolytic degradation in water, such as formoterol. (A1079/20:6-10; A1271/1:53-61; A25650/192:12-18 (Chaudry); A25810/352:4-6 (Barnes).) The only compositional element Dey argues has any appreciable effect on stability of aqueous formoterol formulations is pH. (DBr 9-10.) But Dey's formoterol inhalation solution has the same pH as prior art aqueous formoterol formulations: about 4-6, or more particularly, 5. (A1079/20:1-3; A304/38:1-9.) Dey took the compositional elements of formoterol formulations from the prior art and refrigerated the solution in foil overwrap, obtaining its alleged invention with "improved" stability. (TBr 40-43.)

Dey's arguments incorrectly characterize the stability testing referred to by Teva's experts. (DBr 45-46, 49-51.) The stability testing of formulations prepared according to Gao and Murakami Example 34 (substituting formoterol for a formoterol analog) prove that the formulations taught by the references have the same stability as the formulations in the Asserted Claims. (*See* TBr 49-51.) This testing is not about establishing what a POSA would have known about the formoterol formulations – the testing demonstrates that the "stability" is an inherent property of prior art formulations. The testing also confirms what all

experts agreed on – stability characteristics are an inherent property of aqueous formoterol solutions. (A25601/151:4-17 (Chaudry); A25949-50/488:1-489:4 (Myrdal); A26927/1442:2-19 (Hastedt).)

Dey incorrectly maintains that inherency is not relevant to obviousness unless the inherent property was known to a POSA. (DBr 46.) If this Court accepts Dey's proposition, patentees could extend the patent life of known compositions and formulations based on new measurements of old inherent properties. This Court has made it clear that such measurements do not impart patentability. *See Santarus Inc. v. Par Pharmaceutical, Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012).

Lacking any case law support for its position, Dey resorts to extracting isolated sentences from irrelevant cases and stringing them together in a footnote. (DBr 46 n.8.) *In re Rijckaert* simply says "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency.]" 9 F.3d 1531, 1534 (Fed. Cir. 1993) (quoting *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981) (emphasis and alteration in original))). *Rijckaert* does not apply here, because aqueous formoterol solutions at a pH of about 5 *always* have the same inherent stability. (A25601/151:4-17 (Chaudry); A25949-50/488:1-489:4 (Myrdal); A26927/1442:2-19 (Hastedt).) *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002) is a case about inherent anticipation, and has nothing to

do with obviousness. *Cohesive Technologies, Inc. v. Waters Corp.* merely stands for the fundamental proposition that anticipation and obviousness are two separate conditions for patentability and therefore two separate defenses to infringement. 543 F.3d 1351, 1363 (Fed. Cir. 2008).

Dey's attempts to distinguish the cases Teva cited (DBr 46-49) also fall short. Dey argues that *Santarus* is not relevant because the inherent property claimed was known from another prior art reference. (DBr 47.) The Court did not rely on the reference for its inherent obviousness analysis, but apparently mentioned it to show confirmation of the property, *Santarus*, 694 F.3d at 1354, as Teva does here with the stability testing (*see* TBr 49-51).

Dey (DBr 47) ignores this Court's statement in *In re Napier* that "[t]he inherent teaching of a prior art reference … arises both in the context of anticipation *and obviousness*." 55 F.3d 610, 613 (Fed. Cir. 1995) (emphasis added). The inherent property need not be known to a POSA for the invention to be obvious. *See id.* Rather, there must be some basis for saying a property is inherent. Here, the basis is testimony by the inventor and the experts that stability is inherent. (A25601/151:4-17 (Chaudry); A25949-50/488:1-489:4 (Myrdal); A26927/1442:2-19 (Hastedt).)

Dey attempts to distinguish *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362 (Fed. Cir. 2012); *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011); and *In re Kubin*,

561 F.3d 1351 (Fed. Cir. 2009) by manufacturing differences where none exist. (DBr 48-49.) In each of these cases, Dey admits "the claims recited properties or effects that necessarily resulted from a claimed method of treatment (*Alcon, Kao*) or DNA molecule (*Kubin*)." (DBr 48.) Similarly, here, the claims recite stability that necessarily results from the claimed formulation. (A25601/151:4-17 (Chaudry); A25949-50/488:1-489:4 (Myrdal); A26927/1442:2-19 (Hastedt).)

In *Alcon*, the invalid claims relate to a method of treating human eye allergies comprising stabilizing conjunctival mast cells by topically applying olopatadine. 687 F.3d at 1363-64. Prior art disclosed testing an olopatadine ophthalmic formulation in guinea pig eyes at concentrations overlapping those in several asserted claims but also stated that olopatadine, while a good antihistamine, was not a good mast cell stabilizer. *Id.* at 1365. Despite the reference's statement that olopatadine was not a good mast cell stabilizer, this Court held that a POSA would have been motivated to use olopatadine to treat eye allergies because olopatadine had antihistaminic activity. *Id.* at 1369. The Court explained that the patent defined mast cell stabilization as a property present at the claimed concentrations, so the claimed requirement for mast cell stabilization was inherent in the prior art and added no additional requirements to the invention. *Id.*

In *Kao*, the Court found that a "food effect" limitation in claims to a controlled-release oxymorphone formulation was an inherent property of

oxymorphone itself, and therefore claims requiring the "food effect" were obvious over prior art disclosing all the other claim limitations except the "food effect." 639 F.3d at 1070. The Court explained, "This is not a case where the Board relied on an unknown property of prior art for a *teaching*. Rather, [the reference's] express teachings render the claimed controlled release oxymorphone formulation obvious, and the claimed 'food effect' adds nothing of patentable consequence." *Id.* (emphasis in original).

In *Kubin*, the Court held that claims relating to a polynucleotide encoding a polypeptide binding to a certain protein were not patentable over prior art teaching the polypeptide and how to obtain the polynucleotide encoding it. 561 F.3d at 1353-54, 1357. The Court found that even though none of the prior art taught the claimed protein binding, such binding was a property necessarily present in the polypeptide and added no additional requirement. *Id.* at 1357. Similarly, here, the claimed compositions were anticipated by, or obvious in view of the prior art, and claiming the inherent "stability" adds nothing of patentable consequence.

Because stability is inherent in a composition, the claimed stability is necessarily a property of formoterol formulations having the claimed ingredients. Directly contrary to Dey's assertion that "the requirement that the compositions be 'stable during long term storage' is not a necessary or inherent property of any other limitation of the Asserted Claims" (DBr 48-49), the evidence proved that the

compositional elements in the Asserted Claims and the prior art – formoterol, water, citrate buffer, tonicity agent, and pH 5 – were what provided the inherent stability of the formulation. (A25601/151:4-17 (Chaudry); A25949-50/488:1-489:4 (Myrdal); A26927/1442:2-19 (Hastedt).)

Dey argues that the formulations in Murakami and Gao are not identical to the claimed formulations, so their inherent stabilities are not identical. (DBr 49-50.) This ignores Dr. Myrdal's testimony regarding the stability testing of aqueous formoterol solutions, which confirms the inherent stability of such buffered solutions at pH 5. (A25949-50/488:1-489:4 (Myrdal).) An obvious formulation cannot become nonobvious simply by testing and claiming an inherent property. *Santarus*, 694 F.3d at 1354.

Dey also argues that Murakami teaches only a formulation with a "different compound," (a formoterol analogue), not a formulation comprising formoterol. (DBr 33.) However, Murakami discloses a formulation comprising a formoterol analogue and states that formoterol is a preferred compound. (A25928-29/467:7-468:5 (Myrdal); A286/2:51-57; A304/38:1-9, 53-55.) Just as *Kao's* oxymorphone formulations were obvious in view of oxycodone formulations, formulations comprising formoterol would have been obvious based on the formoterol analogue formulation disclosed in Murakami. 639 F.3d at 1070-71.

C. Simultaneous Invention Demonstrates Obviousness

Dey admits that simultaneous invention can be evidence of obviousness (DBr 60), and as Teva explained (TBr 39-40), the simultaneous "invention" by Sepracor and Dey of a formoterol inhalation solution provides irrefutable evidence of the obviousness of the Patents-in-Suit. Dey's attempt to obscure the obviousness of its own alleged invention by listing other supposedly simultaneous inventions does not alter the obviousness of its alleged invention to a POSA. (DBr 60-62.) The examples Dey cites (calculus, oxygen, and polio vaccine) are unrelated to patentable inventions. Calculus and oxygen are not patentable subject matter, and neither Salk nor Sabin ever patented the polio vaccine.

Dey now suggests that Teva misrepresents the patent and non-patent exclusivities which deterred the development of formoterol formulations in the 1990s. (DBr 59-60.) Dey is incorrect. Dey itself acknowledged:

> [the Murakami] patent had expired by the time that this [Dey's] development story begins in 1999, and there were several more years, but only several more years of so-called statutory exclusivity under the Hatch-Waxman statute in the United States which was possessed by, I believe, a Novartis entity in the United States.

(A25464/14:10-15.) Waiting for these periods to expire was important because "Dey did not want to have a legal battle over clearing patent hurdles or exclusivity hurdles to get their product on the market." (A25464/14:16-18.)

The barriers preventing the development of a formoterol inhalation solution relate to obviousness not because these barriers prevented the development of noninfringing alternatives to Dey's patents, as Dey implies. (DBr 59-60.) Rather, the barriers are relevant because two independent companies, Dey and Sepracor, developed Dey's alleged invention just as these barriers were expiring. (*See* A25498-99/48:20-49:7; 25530-32/80:1-82:8 (Chaudry); A7831/227:25-228:5 (Wald).) The "invention" was obvious all along; only these barriers kept it from being developed sooner.

D. Objective Indicia Are Not Persuasive of Nonobviousness

1. Dey Did Not Establish a Nexus Between Objective Indicia and the Asserted Claims

Dey contends that by offering evidence that Perforomist® practices the claimed invention it has shifted the burden to Teva to demonstrate a lack of nexus. (DBr 53-54.) Dey is wrong. The burden is on Dey to establish a nexus, and Dey is entitled to a presumption of nexus only "[i]f [it] can demonstrate that the commercial success of its product derives from the claimed invention and is attributable to something disclosed in the patent *that was not readily available in the prior art*." *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (emphasis added); *see also Sparton Corp. v. U.S.*, 89 Fed. Cl. 196, 238-39 (2009). Dey has not made the requisite *prima facie* showing of a nexus because the Asserted Claims are directed to various combinations of well-

known components (e.g. formoterol, water, tonicity agent, buffer, pH 5), which have an inherent stability. These features and combinations make no contribution to the invention over the prior art. (TBr 44-45; 58-60.) By failing to carry its burden, Dey established neither commercial success nor long felt need. *Id.*

2. Perforomist® Was Not a Commercial Success

Dey's supposed commercial success (DBr 53) is illusory. Perforomist® failed at every point to meet sales expectations. (*See* A26520-21/1047:21-1048:12; A26524-25/A1051:1-1052:7; 26530-542/1057:9-1069:4 (David); A39639-41.) With this track record of overestimating future sales, Dey's projection of future net sales are mere conjecture and should be disregarded.

3. There Was No Long Felt Need

By the time Dey and Sepracor worked on their formoterol inhalation solutions, the supposed need for an easy to use inhalation product for COPD was already met by the product Serevent® in conjunction with a valved chamber. Both Teva's and Dey's experts agree on this. (A26311-12/845:15-846:14 (Hendeles); A25740/282:2-5; A25855/397:13-19 (Barnes).)

Dey conveniently ignores that its own expert, Dr. Barnes, acknowledged that "Serevent® is very similar to formoterol in its duration of action" (A25740/282:4-5), and agreed that with valved chambers "[n]ormally, the patient would press the canister into the chamber and then breathe from the valve into the

lung. So, … *it gets around the problem of coordination between activating the device and inhaling.*" (A25855/397:13-19, emphasis added.) Dr. Barnes also confirmed that any patient who might be prescribed a nebulizer could also use an MDI with a valved chamber. (A25751/293:13-20.)

As the parties' experts agree on these points, the District Court erred in finding there was a "long felt need" met by Dey's product. *See In re PepperBall Techs., Inc.,* 469 Fed. Appx. 878, 882 (Fed. Cir. 2012) (affirming finding of obviousness where "others had previously solved the long-felt need").

4. Copying Is Irrelevant to Obviousness

Contrary to Dey's contentions (DBr 57-58), this Court has provided explicit guidance that in ANDA litigation, copying of a reference-listed drug does not demonstrate nonobviousness. *Bayer Healthcare Pharms., Inc. v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013). The holding in *Bayer* provides no indication that the decision was limited to accused infringers who copy only the "active ingredient," "route of administration," "dosage form," or "strength," as Dey now implies. (DBr 57-58.) The District Court erred in relying on Teva's alleged copying as an objective indicium of obviousness.

CONCLUSION

For the foregoing reasons and the reasons set out in Teva's opening brief on appeal, Teva respectfully requests that the District Court's judgment of

infringement be reversed, the Asserted Claims found invalid, or, if necessary, the case be remanded for further proceedings based on the proper construction of the terms used in the Asserted Claims.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2014, the foregoing *Non-Confidential Reply Brief of Defendants-Appellants Teva Parenteral Medicines, Inc., Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc.* was filed electronically with the U.S. Court of Appeals for the Federal Circuit by means of the Court's CM/ECF system and served on the following counsel of record, by means of electronic mail and Pre-Paid U.S. First Class Mail, as well as by the Court's CM/ECF system, which should have sent a Notice of Docket Activity:

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